ORIGINAL RESEARCH

# Comparison of outcomes with multifocal intraocular lenses: a meta-analysis

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Correspondence: Gilles Berdeaux Alcon France, 4 rue Henri Sainte Claire Devill, 92563 Rueil-Malmaison, Cedex, France Tel +33 I 47 I0 48 60 Fax +33 I 47 I0 27 70 Email gilles.berdeaux@alconlabs.com **Purpose:** To compare the clinical outcome of different multifocal intraocular lenses (IOLs) based on information reported in the international literature.

**Methods:** All comparative clinical trials that involved implanting at least one multifocal IOL in patients with cataract or presbyopia were extracted from the literature. Clinical outcomes included uncorrected near visual acuity, uncorrected distance visual acuity, visual acuity, spectacle independence, and halos. Random effects meta-analyses were conducted to compare outcomes for the different IOL types.

**Results:** Twenty papers were identified describing 11 monofocal IOLs and 35 multifocal IOLs (19 diffractive, including 12 ReSTOR<sup>®</sup>, 14 refractive, and two accommodative) patient cohorts. Multifocal and monofocal uncorrected distance visual acuity was 0.165 (0.090–0.240) and 0.093 (0.088–0.098), respectively. Compared with monofocal IOLs, multifocal IOLs produced better uncorrected near visual acuity (0.470 [0.322–0.618] versus 0.141 [0.131–0.152]; P < 0.0001), resulting in higher spectacle independence (incidence rate ratio [IRR] 3.62 [2.90–4.52]; P < 0.0001). Compared with refractive multifocal IOLs, diffractive multifocal IOLs produced a similar uncorrected distance visual acuity (0.105 [0.098–0.111] versus 0.085 [0.029–0.140];  $P \le 0.78$ , not significant) and better uncorrected near visual acuity (0.217 [0.118–0.317] versus 0.082 [0.067–0.098]; P < 0.0001) resulting in higher spectacle independence (IRR 1.75 [1.24–2.48]; P < 0.001). Compared with other multifocal IOLs, ReSTOR produced a better uncorrected near visual acuity (0.067 [0.059–0.076] versus 0.093 [0.088–0.098]; P < 0.0001) and better uncorrected near visual acuity (0.217 [0.118–0.317] versus 0.082 [0.067–0.098]; P < 0.0001) resulting in higher spectacle independence (IRR 1.75 [1.24–2.48]; P < 0.001). Compared with other multifocal IOLs, ReSTOR produced a better uncorrected near visual acuity (0.064 [0.046–0.082] versus 0.141 [0.131–0.152]; P < 0.0001) and better uncorrected near visual acuity (0.264 [0.046–0.082] versus 0.141 [0.131–0.152]; P < 0.006), resulting in higher spectacle independence (IRR 2.06 [1.26–1.36]; P < 0.004). Halo incidence rates with different types of multifocal implants did not differ significantly.

**Conclusion:** Multifocal IOLs provide better uncorrected near visual acuity than monofocal IOLs, leading to less need for spectacles. Multifocal IOL design might play a role in postsurgical outcome, because better results were obtained with diffractive lenses. ReSTOR showed better uncorrected near visual acuity, uncorrected distance visual acuity, and higher spectacle independence rates compared with other multifocal IOLs.

**Keywords:** multifocal implants, meta-analysis, uncorrected near visual acuity, uncorrected distance visual acuity, spectacle independence, patient satisfaction

## Introduction

An estimated 20.5 million Americans older than 40 years have cataract in at least one eye.<sup>1</sup> While cataract is the leading cause of blindness worldwide,<sup>2,3</sup> most populations in developed Western countries have access to cataract surgery (eg, 6.1 million [5.1%] of American citizens have pseudophakia/aphakia). The total number of Americans with cataract is predicted to increase to 30.1 million by 2020, of whom 9.5 million are expected to

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have pseudophakia.<sup>1</sup> More than 80% of patients regain good best-corrected visual acuity (visual acuity  $\geq 8/10$ ) after cataract surgery, depending on other ocular pathology and duration of follow-up.<sup>4-8</sup>

Traditional intraocular lenses (IOLs) are monofocal, and after implantation most patients need spectacles, at least for near vision. Multifocal IOLs are intended to free patients from spectacles after presbyopia or cataract surgery by applying the principle of simultaneous vision.<sup>9</sup> Early multifocal IOLs were associated with loss of clarity and poor accommodation, reduced contrast sensitivity, and complaints of halos and glare. Improvements in intraocular lens technology have enabled cataract patients to be implanted with multifocal IOLs to provide better visual acuity at various distances and a degree of spectacle independence.<sup>10</sup>

Today, multifocal IOLs produce functional near and distance vision and acceptable levels of patient satisfaction in everyday practice.<sup>11-14</sup> However, reviews on the clinical consequences of multifocal implantations are rare.<sup>15</sup>

Many IOL clinical trials have been performed, but to our knowledge, no relevant meta-analysis has been reported. Our objective was to conduct a meta-analysis of published comparative clinical trials in which at least one patient group was implanted with multifocal implants bilaterally.

# Materials and methods Bibliographic research

An extensive literature review was performed through Medline and most recently updated on June 30, 2009. The following multifocal IOL names were used as keywords: Acrilisa® (Carl Zeiss Meditec, La Rochelle, France), Diffractiva® (HumanOptics, Erlangen, Germany), Rayner® (Rayner Intraocular Lenses Ltd., Hove, UK), ReSTOR® (Alcon Inc., Fort Worth, TX), Rezoom® (Abbott Medical Optics, Santa Ana, CA), and Tecnis® (Abbott Medical Optics), together with keywords focusing on comparative clinical trials, ie, "cataract surgery", "comparison", "multifocal", and "visual acuity". Abstracts were scrutinized and full articles ordered and analyzed in depth if they reported comparative studies in adult patients.

Inclusion criteria were publication in the French or English language, bilateral implantation of the same IOL, use of Tecnis, Acrilisa, Rezoom, Diffractiva, Rayner, or ReSTOR implants, and publication from 2000 onwards.

Exclusion criteria included comparison of different populations, double implantation in the same eye, double reporting, explantation of the implant, in vitro studies, no aggregated results, noncomparative studies, unilateral implantation, and use of a refractive procedure (eg, Lasik). All available data from the selected articles were extracted and tabulated with respect to each study's identity, its design (prospective or retrospective, randomized or not randomized), IOL names and type (monofocal or multifocal; diffractive or refractive), reasons for IOL implantation, number of patients at baseline and at final follow-up, average follow-up duration, final overall patient satisfaction, spectacle dependency, uncorrected distance visual acuity, uncorrected intermediate visual acuity, uncorrected near visual acuity, and the number of patients reporting "halos".

## Data analysis

Outcome variables of the study were as follows:

- Uncorrected distance and near visual acuities converted to LogMAR equivalents, as described in detail elsewhere,<sup>16</sup> when expressed in a different unit.
- Freedom from spectacles (independence), separately analyzed for distance and reading spectacles. It should be noted, however, that most studies combined all types of spectacles to express an overall need for spectacles, instead of providing specific information on distance versus reading spectacles.
- Patient satisfaction; given that variations between studies existed, to assess patient satisfaction, we standardized measurements according to the range of the measurements reported in each study.
- Presence of halo, which was reported using various definitions among the studies. Prevalence (presence versus absence of halos) was reported in this study.

We compared the aforementioned outcomes for the following subgroups of IOL implants: monofocal versus multifocal implants; diffractive versus refractive multifocal implants (data were insufficient to assess the effects of accommodative implants separately); and ReSTOR versus other multifocal implants. ReSTOR outcomes were highlighted because they relate to a new type of multifocal apodized IOL.

## Statistical analysis

We used random effects models<sup>17,18</sup> to obtain pooled estimates of visual acuity with 95% confidence intervals (CI), and tested for statistically significant differences between the estimates with respect to each IOL subgroup.

We used random effects Poisson regression models to compare the effect of IOL implant type on the need for spectacles. The outcome of interest was the number of patients needing spectacles, with study effects taken into account by the random effects component of the models. The exposure

variable for the Poisson models was defined as the product of the number of patients receiving a given implant and the average period of follow-up for each study. Similarly, we used random effects Poisson regression models to compare overall patient satisfaction and the presence of halo across subgroups of implants.

Forest plots were used to present the results. The lines represent the estimates from different studies and their CI. The boxes represent graphically the weight given to each study in calculating the pooled estimate for a given outcome. This weight is essentially a function of the number of patients followed up in different studies.

# **Results** Bibliographic research

Initial electronic searches identified 197 titles or abstracts. Complete copies of all possibly relevant papers were obtained, according to the criteria specified earlier. Fifty-one papers appeared to meet the inclusion criteria for this review.

Twenty of the 51 studies were included in the metaanalysis. The excluded 31 papers finally did not meet the inclusion and exclusion criteria. Reasons for exclusion were, as follows: a different IOL in each eye (n = 7); reimplantation in one eye (n = 1); no comparison IOL (n = 6); double reporting (n = 4); comparison of different populations (n = 1); comparisons of monofocal IOLs (n = 2); either no data or aggregated data (n = 8); results after Lasik or another procedure (n = 2); and in vitro results (n = 1).

## Descriptive data analysis

Twenty studies were included in the meta-analysis,<sup>19–38</sup> of which 16 were prospective studies (80%) and four were retrospective (Table 1). Eight (50%) of the prospective studies were randomized. Data were collected from 46 patient groups, comprising 35 multifocal implant groups (76.1%) and 11 monofocal implant groups (23.9%). Among the multifocal implant groups, 19 were implanted with diffractive IOLs, 14 with refractive IOLs, and two with accommodative IOLs. ReSTOR was implanted in 12 of these groups (34.3%). Accommodative implants were studied in 26 patients only, and so were not analyzed as a specific group. Uncorrected distance vision acuity was described for 30 groups and near vision acuity for 23 groups.

All except six publications reported patient satisfaction as percentages of patients "satisfied" or "very satisfied". Four papers isolated "patient satisfaction with vision" from a broader assessment of "overall satisfaction". One paper rated satisfaction on a scale from 0 to 10 (maximal satisfaction). Finally, one paper used a questionnaire yielding a global measure of overall satisfaction that included a validated "VF-14 index of visual function".

Fourteen (70%) of the 20 publications assessed spectacle independence, expressed in most cases as the number, or percentage, of patients who at the end of the follow-up period needed spectacles for reading or distance vision. Other studies asked patients how often they wore spectacles and gave them the response options of "always", "occasionally", or "never". Distance vision (spectacle independence) was not stated by 10 studies, and only four studies gave both distance and near vision, by indicating patients requiring the respective correction spectacles. Visual disturbances, which could be night-time halos, moderate halos, or severe halos, were reported by 10 studies (50%). Table 2 summarizes the characteristics of all 20 publications included in this metaanalysis and provides references to them.

## Visual acuity

Table 3 shows pooled estimates of random effects, with 95% CI, for uncorrected distance and near visual acuity (LogMAR scale) after monofocal and multifocal IOL implants. Separate estimates are shown for diffractive and refractive multifocal implants and for ReSTOR.

Table 4 shows that multifocal and monofocal uncorrected distance visual acuity was 0.165 and 0.093, respectively. Between the multifocal implants, there was no statistically significant uncorrected distance visual acuity difference (P = 0.78), or between diffractive IOLs (average LogMAR 0.105) and refractive IOLs (average LogMAR 0.085). However, uncorrected distance visual acuity was significantly better with ReSTOR (average LogMAR 0.067) as compared with other multifocal implants (P < 0.001). Table 4 also shows that uncorrected near visual acuity was significantly better (P < 0.001) after multifocal implants (average Log-MAR 0.141) than monofocal IOLs (average LogMAR 0.470). Moreover, with multifocal implants, uncorrected near visual acuity was significantly better (P = 0.002) with diffractive IOLs (average LogMAR 0.082) than refractive IOLs (average LogMAR 0.217). Furthermore, uncorrected near visual acuity was significantly better (P = 0.006) after ReSTOR implants (average LogMAR 0.064) than after all other multifocal IOLs. Forest plots of uncorrected near and distance visual acuity are reported in Figures 1-4.

## Freedom from spectacles

Table 5 shows the results of random effects Poisson regression models comparing the incidence of no spectacle require-

Table I Characteristics, references, and available results of the published studies

Reference	Design	IOL	Trt	Satisfaction	Spectacle classification	Halo
Bi et al <sup>19</sup>	Р	ReSTOR vs Acrysof SN60AT	N	Satisfaction with reading acuity	Spectacle independence	N
Chiam et al <sup>20</sup>	Р	ReSTOR vs Rezoom	Y	Overall satisfaction	Spectacle independence	Y
Toto et al <sup>21</sup>	Р	ReSTOR vs Tecnis	Y			Ν
Souza et al <sup>22</sup>	Р	ReSTOR vs Acrysof SA60AT	Ν			Y
Vingolo et al <sup>23</sup>	R	ReSTOR vs Acrysof SA60AT	n.m.		Spectacle independence	Y
Alfonso et al <sup>24</sup>	Р	ReSTOR SA60D3 vs ReSTOR SN60D3	Ν	Overall satisfaction	Near distance spectacle independence	Ν
Chiam et al <sup>25</sup>	Р	ReSTOR vs Acrysof SA60AT	n.m.	% of patients completely or very satisfied	Spectacle independence	Y
Pepose et al <sup>26</sup>	Ρ	ReSTOR vs Rezoom vs Crystalens	Ν	% of patients completely or very satisfied	Near and distance spectacle independence	Ν
Mester et al <sup>27</sup>	Р	Tecnis vs Array	Y	% of patients completely or very satisfied	Spectacle independence	Y
Brydon et al <sup>28</sup>	R	Array vs SI-30NB	Ν	VF14 index		Ν
Chen et al <sup>29</sup>	R	Monofocal Acrysof vs Array	Ν	% of patients satisfied with results	Spectacle independence	Ν
Sen et al <sup>30</sup>	Р	Array vs SI-40NB	Y	% of patients completely or very satisfied		Y
Javitt et al <sup>31</sup>	Р	Array vs AMO	Y	Satisfaction level graded from 0 to 10	Spectacle independence	Ν
Cochener et al <sup>38</sup>	Р	ReSTOR vs Acrysof MA60BM	Ν		Spectacle independence	Y
Alio et al <sup>37</sup>	Ρ	Crystalens (AT45) vs Array SA40N vs Acritec twinset	Ν			Y
Cillino <sup>36</sup>	Ρ	AR40 (AMO) vs Array SA40N vs Rezoom (AMO) vs Tecnis ZM900	Y	Overall satisfaction	Full spectacle independence	Y
Zelichowska et al <sup>35</sup>	R	ReSTOR SN60D3 vs Rezoom	n.m.			Ν
Barisic et al <sup>34</sup>	Р	Tecnis multifocal vs Rezoom	Y		Spectacle independence	Ν
Chang-David <sup>33</sup>	Р	ReSTOR vs Rezoom	Ν		Spectacle independence	Y
Martinez-Palmer et al <sup>32</sup>	Ρ	Tecnis Z9000 vs Tecnis ZM900 vs Rezoom vs Acritec twinset	Y		Full spectacle independence	Ν

Abbreviations: n.m., not mentioned; P, prospective; R, retrospective; Trt, treatment affected at random; vs, versus; Y, yes; N, no; IOL, imtraocular lens implant.

ment after different IOL implants. In general, patients with multifocal IOL implants, especially those with diffractive implants, were most likely not to need spectacles. Estimates varied for near and distance vision spectacles, compared with all spectacles combined, with most estimates specific to the two spectacle types not reaching statistical significance, probably because too few specific data were available for analysis. Overall, however, patients with multifocal implants were 3.6 times more likely not to need spectacles (incidence rate ratio [IRR] 3.62, 95% CI: 2.90–4.52).

Diffractive IOL implants were associated with a 1.75-times higher likelihood of spectacle independence (IRR 1.75, 95% CI: 1.24–2.48) than refractive implants. Also, patients implanted with ReSTOR had a more than two-fold higher incidence of spectacle independence compared with other multifocal IOLs (IRR 2.06, 95% CI: 1.26–3.36).

#### **Table 2** Characteristics of the implants included in the 20 articles

#	Reference	IOL	Туре	MIOL type	Follow-up (weeks)	Patients (n)
3	Bi et al <sup>19</sup>	ReSTOR	MIOL	Diffractive	12	20
		Acrysof	Mono		12	18
		SN60AT				
5	Chiam et al <sup>20</sup>	ReSTOR	MIOL	Diffractive	24	50
		Rezoom	MIOL	Refractive	24	50
3	Toto et al <sup>21</sup>	ReSTOR	MIOL	Diffractive	24	14
		Tecnis ZM 900	MIOL	Diffractive	24	14
,	Souza et al <sup>22</sup>	ReSTOR	MIOL	Diffractive	16	24
		Acrysof	Mono		16	15
		SA60AT				
0	Vingolo et al <sup>23</sup>	ReSTOR	MIOL	Diffractive	24	50
		SA60D3				
		Acrysof	Mono		24	20
		SA60AT	1 Iono			20
I	Alfonso et al <sup>24</sup>	ReSTOR	MIOL	Diffractive	24	325
1	Alloliso et al		HIOL	Dimactive	24	525
		SA60D3	MICI	D://	24	225
		ReSTOR	MIOL	Diffractive	24	335
~		SN60D3		D://	0	40
9	Blaylock <sup>41</sup>	ReSTOR	MIOL	Diffractive	8	40
		SN60D3				
		Acrysof	Mono		8	40
		SA60AT				
25	Pepose et al <sup>26</sup>	ReSTOR	MIOL	Diffractive	20	12
		Rezoom	MIOL	Refractive	20	14
		Crystalens	MIOL	Accommodative	20	14
		(AT45)				
2	Mester et al <sup>27</sup>	Tecnis ZM900	MIOL	Diffractive	24	23
		Array SA40	MIOL	Refractive	24	24
6	Brydon et al <sup>28</sup>	Array (SA40N)	MIOL	Refractive	11	15
	·	SI-30NB	Mono		10	13
8	Chen et al <sup>29</sup>	Monofocal	Mono		nm	20
	Acrysof					
		Array	MIOL	Refractive	nm	20
1	Sen et al <sup>30</sup>	Array (SA40N)	MIOL	Refractive	4	35
		SI-40NB	Mono		4	40
3	avitt et al <sup>31</sup>	Array (SA40N)	MIOL	Refractive	12	123
	juvice ee ui	PhacoFlex	Mono	Rendetive	12	109
		SI40NB	1 Iono		12	107
3	Cochener et al <sup>38</sup>	ReSTOR	MIOL	Diffractive	21	499
5	Cochener et al	Acrysof	Mono	Dimactive	21	173
		,	110110		21	175
-	Alia at a 137	MA60BM	MICI	A	40	12
5	Alio et al <sup>37</sup>	Crystalens AT45	MIOL	Accommodative	48	12
		Array SA40N	MIOL	Refractive	48	16
	2	Acritec twinset	MIOL	Diffractive	48	12
6	Cillino et al <sup>36</sup>	AR40 (AMO)	Mono		48	15
		Array SA40N	MIOL	Refractive	48	16
		Rezoom (AMO)	MIOL	Refractive	48	15
		Tecnis ZM900	MIOL	Diffractive	48	16
7	Zelichowska et al <sup>35</sup>	ReSTOR	MIOL	Diffractive	24	23
		SN60D3				
		Rezoom	MIOL	Refractive	24	23
9	Barisic et al <sup>34</sup>	Tecnis multifocal	MIOL	Diffractive	24	50
		Rezoom	MIOL	Refractive	24	50
0	Chang-David <sup>33</sup>	ReSTOR	MIOL	Diffractive	24	15
		Rezoom	MIOL	Refractive	24	15
d l	Martinez-Palmer et al <sup>32</sup>	Tecnis Z9000	Mono		12	24
		Tecnis ZM900	MIOL	Diffractive	12	26
		Rezoom	MIOL	Refractive	12	32
		Acritec twinset	MIOL	Diffractive	12	32

Abbreviations: IOL, intraocular lens implant; MIOL, multifocal intraocular lens implant; nm, not mentioned.

#### Table 3 Characteristics of the 46 groups

	Patients (n)	Follow-up	Follow-up Average UDVA		Satisfaction	Need for spectacle
	(total patients)	(weeks)	(LogMAR)	(LogMAR)	rate	(all spectacles)
Monofocal	(486)					
groups						
n	11	10	5	5	8	7
Mean # of patients (SD)	44.3 (50.8)	16.9 (12.4)	0.27 (0.25)	0.47 (0.124)	0.8 (0.23)	0.78 (0.22)
(min–max)	(13-273)	(4-48)	(0.11–0.7)	(0.3-0.61)	(0.31-0.99)	(0.45-0.96)
Multifocal	(2055)		, , , , , , , , , , , , , , , , , , ,	. ,	. ,	. ,
groups						
n	35	34	25	18	23	19
Mean (SD)	58.7 (106.5)	24.4 (12.5)	0.09 (0.08)	0.15 (0.098)	0.87 (0.08)	0.31 (0.2)
(min-max)	(12-499)	(4-48)	(-0.066-0.245)	(0.013-0.403)	(0.64-0.99)	(0.08-0.67)
Diffractive	(1580)					
groups						
n	19	19	14	9	11	11
Mean (SD)	83.2 (139.3)	23 (10.3)	0.109 (0.065)	0.091 (0.054)	0.90 (0.06)	0.2 (0.13)
(min–max)	(12-499)	(8–48)	(0.03-0.245)	(0.013-0.156)	(0.82-0.99)	(0.08–0.56)
Refractive	(448)					
groups						
n	14	13	9	7	11	8
Mean (SD)	32 (29)	24.8 (14.7)	0.074 (0.088)	0.232 (0.099)	0.93 (0.09)	0.47 (0.14)
(min–max)	(14–123)	(4–48)	(-0.066-0.207)	(0.11–0.403)	(0.64–0.94)	(0.3–0.67)
ReSTOR	(1408)					
groups						
n	12	12	8	7	8	6
Mean (SD)	117.3 (168)	20.5 (5.5)	0.069 (0.031)	0.08 (0.055)	0.9 (0.07)	0.16 (0.06)
(min–max)	(12-499)	(8–24)	(0.03-0.13)	(0.013-0.15)	(0.82-0.99)	(0.08-0.27)

Abbreviations: UDVA, uncorrected distance visual acuity; UNVA, uncorrected near visual acuity; SD, standard deviation; min, minimum; max, maximum.

## Patient satisfaction and halo

Results of patient satisfaction and presence of halo analyses are shown in Tables 5 and 6. No statistically significant differences between implant types were found for patient satisfaction or halo reports. In most cases, point estimates (IRRs) were close to the null value (1.0), except between diffractive versus refractive IOL implants with regard to halo. Diffractive implants were associated with a lower incidence rate of halo as compared with refractive implants (IRR 0.71, 95%) CI: 0.48–1.05), but the difference did not reach statistical significance (P = 0.087).

### **Discussion**

Our study compared vision outcomes after multifocal IOL or monofocal IOL implants, and outcomes after multifocal implants differing in physical properties and other characteristics. In this meta-analysis, because we found very few trials comparing head to head monofocal IOLs, we made the

Table 4 Random effects p	pooled estimates of uncorrected distance	e and near visual acuity for IOL implants
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IOL implant	Distance visual acuity			Near visual acuity		
	Mean LogMAR	95% CI	P*	Mean LogMAR	95% CI	P*
Monofocal	0.165	0.090-0.240	< 0.00 l	0.470	0.322-0.618	< 0.001
Multifocal, all	0.093	0.088-0.098		0.141	0.131-0.152	
Multifocal,	0.105	0.098-0.111	0.78	0.082	0.067-0.098	0.002
diffractive						
Multifocal,	0.085	0.029-0.140		0.217	0.118-0.317	
refractive						
ReSTOR	0.067	0.059-0.076	<0.001	0.064	0.046-0.082	0.006

**Notes:** \**P* values for statistical test of the significance of the differences between monofocal versus multifocal, diffractive versus refractive, and ReSTOR other multifocal IOL implants, respectively.

Abbreviations: IOL, intraocular lens; CI, confidence interval.

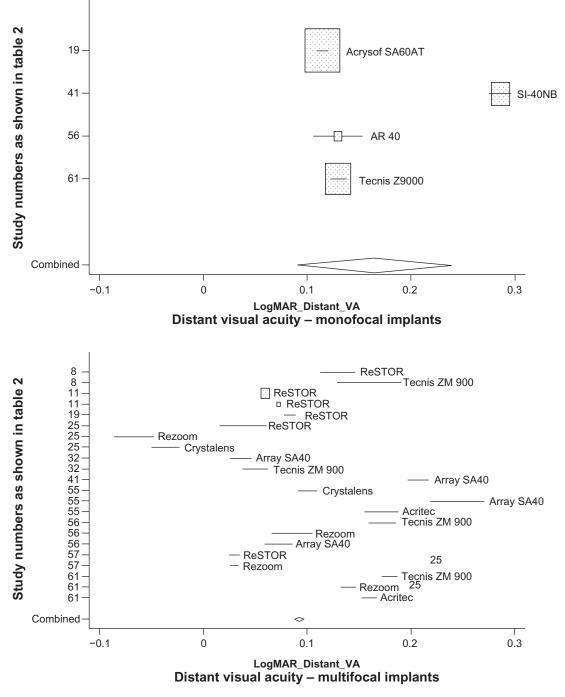


Figure I Uncorrected distant visual acuity: random effects pooled LogMAR estimates for monofocal vs multifocal intraocular lens implants. The y-axis denotes the estimates obtained in different studies as well as the combined (pooled) estimate.

decision to use monofocal IOL arms as a common arm to do indirect comparisons among multifocal IOLs. We did not compare the different types of monofocal IOLs, because this was not our objective and because the experimental design was not appropriate for us to do so.

Although we identified an important number of relevant studies (n = 20), it should be noted that most did not randomize

treatments, which could be considered as poor evidence reporting. However, this can be explained by certain ethical constraints. Randomization is acceptable in the early development of an IOL, from the patient's point of view, because the associated benefit–risk ratio has to be quantified. Subsequently, however, it is much more difficult to promise patients spectacle independence when treatments are randomized in a clinical trial

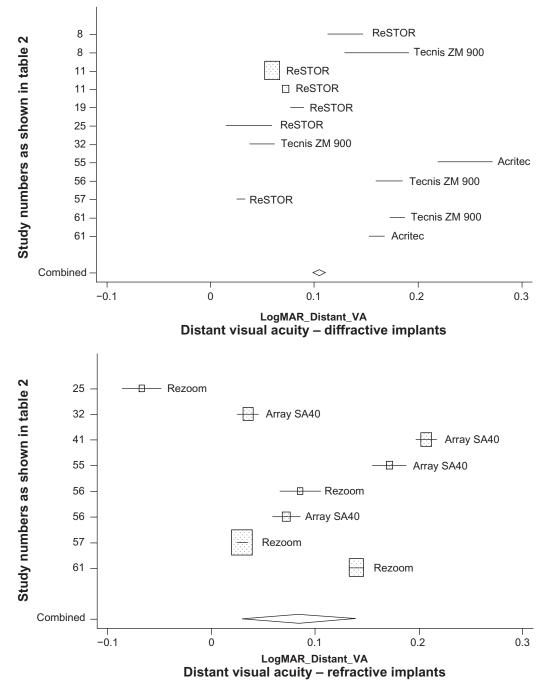


Figure 2 Uncorrected distant visual acuity: random effects pooled LogMAR estimates for diffractive, refractive, and ReSTOR multifocal intraocular lens implants. The y-axis denotes the estimates obtained in different studies as well as the combined (pooled) estimate.

and knowing that only patients given a multifocal IOL implant can enjoy freedom from spectacles. This explains why most trials analyzed by this meta-analysis were not randomized.

We found better uncorrected distance visual acuity following multifocal IOL implants than after monofocal implants, which was unexpected from an optics standpoint. It might be that surgeons implanting multifocal IOLs promised their patients freedom from spectacles, although this did not apply to monofocal implants. Perhaps they then performed more precise biometric assessments after the multifocal IOLs in order to ensure that the patients would not need spectacles. This would explain the better uncorrected distance visual acuity findings.

Patient satisfaction was high for all implants, with no difference observed between IOLs. On the top of this ceiling effect, it must be recalled that satisfaction reports were not obtained in a uniform manner across studies, which was likely to engender high uncontrolled variability. Also, satisfaction questions concerned surgical outcomes and did not refer to the

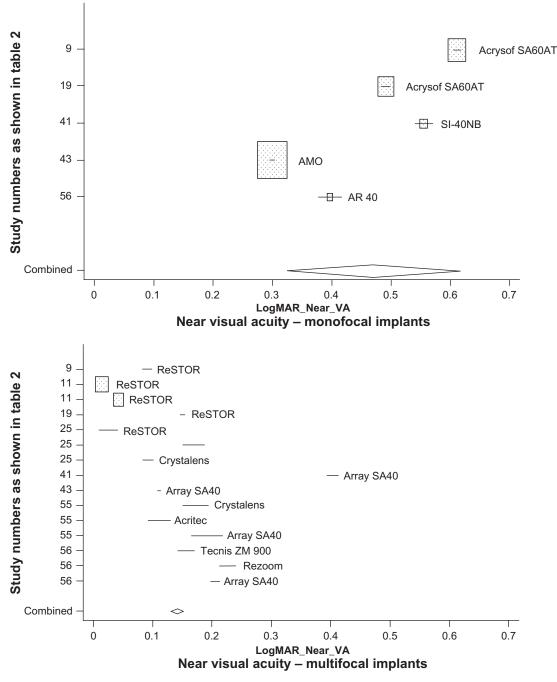


Figure 3 Uncorrected near visual acuity (VA): random effects pooled LogMAR estimates for monofocal vs multifocal intraocular lens implants. The y-axis denotes the estimates obtained in different studies as well as the combined (pooled) estimate.

IOLs implanted. Patients undergoing simple cataract surgery always express high levels of satisfaction because their corrected visual acuity improves dramatically. Hence, an outcome questionnaire dedicated to refraction evaluation, such as the NEI-RQL-42, would be more appropriate to capture a patient's perceived benefit of being free from spectacles.<sup>39,40</sup>

The main limitation of our study was the distribution of patients between the clinical trials of the different IOL implants. In particular, the numerically superior diffractive multifocal IOLs was especially due to a high number of patients implanted with ReSTOR as compared with the alternative diffractive implant, Tecnis, which was studied in almost 10 times fewer patients than ReSTOR. Also, the total number of patients recruited in clinical trials of all refractive multifocal IOL implants was half that for ReSTOR. Given the aforementioned figures, it would appear that our statistical analysis was more powerful with regard to objective findings for ReSTOR than for the other multifocal IOLs when taken

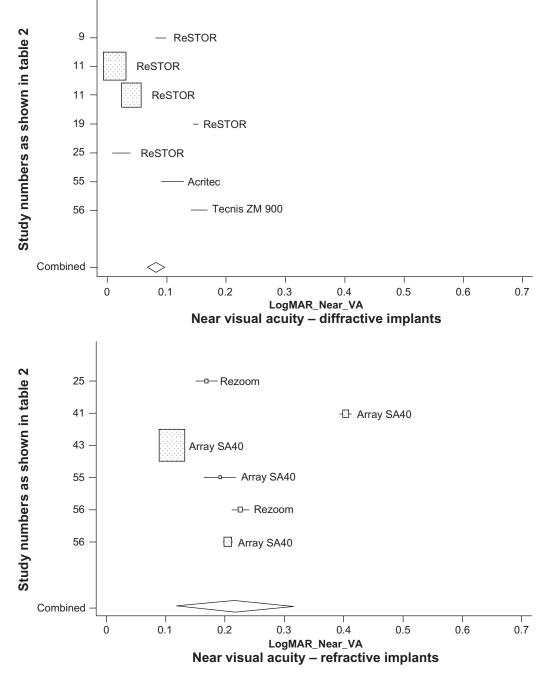


Figure 4 Uncorrected near visual acuity: random effects pooled LogMAR estimates for diffractive, refractive, and ReSTOR multifocal IOL implants. The y-axis denotes the estimates obtained in different studies as well as the combined (pooled) estimate.

Table 5         Random effects         Poisson regression estimates for comparison of the probability (incidence) of independence from no distance,
reading, and all spectacles combined for different subgroups of IOL implants

IOL implant	Distance spectacles		Reading spectacles		All spectacles	cles
	IRR	95% CI	IRR	95% CI	IRR	95% CI
Monofocal	1.00	Reference	1.00	Reference	1.00	Reference
Multifocal, all	1.69	1.06-2.70	1.37	1.02-1.84	3.62	2.90-4.52
Multifocal diffractive	1.54	0.36-6.61	2.61	0.82-8.29	1.75	1.24-2.48
Multifocal refractive	1.00	Reference	1.00	Reference	1.00	Reference
ReSTOR*	Not	estimable**	1.51	0.43-5.24	2.06	1.26-3.36

Notes: \*Comparison between ReSTOR other multifocal IOL implants; \*\*Insufficient data for estimating the IRR. Abbreviations: IOL, intraocular lens; CI, confidence interval; IRR, incidence rate ratio.

Table 6Random effectsPoisson regression estimates forcomparison of the probability (incidence) of satisfaction and ofpresence of halo for subgroups of IOL implants

IOL implant	Satisf	action	Halo		
	IRR	95% CI	IRR	95% CI	
Monofocal	1.00	Reference	1.00	Reference	
Multifocal all	1.03	0.90-1.17	1.13	0.91-1.39	
Multifocal diffractive	1.05	0.85-1.31	0.71	0.48-1.05	
Multifocal refractive	1.00	Reference	1.00	Reference	
ReSTOR	1.01	0.75-1.36	0.93	0.54-1.60	

Note: \*Comparison between ReSTOR and other multifocal IOL implants. Abbreviations: CI, confidence interval; IRR, incidence rate ratio.

separately. Another limitation was the variability of measurement parameters, especially with respect to spectacle independence which was not expressed similarly across studies.

To our knowledge, no previous meta-analysis has been applied to the present outcomes with multifocal implants. The single existing review article<sup>15</sup> did not involve statistical analysis. Consequently, we could not compare our results with other scientific sources.

On the basis of the present results, we can conclude that multifocal IOLs offer patients better near uncorrected visual acuity than do monofocal implants. Also, ReSTOR provided significantly better visual acuity than other multifocal IOLs.

Spectacle independence was achieved more frequently with multifocal implants than monofocal IOLs, and by multifocal diffractive implants than refractive IOLs. ReSTOR patients also experienced greater freedom from spectacles than patients implanted with other multifocal IOLs. The number of patients observed was insufficient to achieve statistical significance with respect to types of spectacles required (near or distance vision). Also, statistical significance was not attained for patient satisfaction or halo reports. A trend (P=0.087) was observed, suggesting fewer halos with multifocal diffractive implants compared with refractive IOLs. Hence, the design of an implant could also play a role in the outcome following a multifocal IOL implant.

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## Disclosure

GB is an employee of Alcon, France. The other authors disclose no conflicts of interest.

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